4-5-05



TFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Bruce K. Redding JR.

Serial No.: 10/782,398

Filed: February 18, 2004

Attorney Docket No.: 04-40081-US

Group Art Unit: 3763

TITLE: ULTRASONICALLY

ENHANCED SALINE TREATMENT FOR

BURN DAMAGED SKIN

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97(c)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The references listed in Form PTO-1449 were submitted by the Applicant or cited by the examiner in prior application Serial Nos. 09/939,435, 09/939,506, 09/939,507 and 10/345,825. The Information Disclosure Statement submitted in the earlier applications complies with 37 C.F.R. § 1.98(a)-(c). Accordingly, pursuant to 37 C.F.R. § 1.98, copies of the aforementioned documents are <u>not</u> submitted herewith.

While the information cited in this Information Disclosure Statement may be "material" pursuant to 37 C.F.R. § 1.56, the filing of this reference should not be construed to be an admission that any patent, publication or other information referred to herein is, or is considered to be, either "prior art" for this invention or otherwise material to the patentability of this invention as defined in 37 C.F.R. § 1.56(b).

Attorney Docket No. 04-40081-US

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Nos. 4,878,892, 5,328,452, 6,614,143, 6,569,099, 6,663,554 and 5,135,479 contained in this information disclosure statement were cited in an International Search Report more than three months prior to the filing of this information disclosure statement. Copies of U.S. Patents Nos. 4,878,892, 5,328,452, 6,614,143 and 5,135,479 are not submitted because they were submitted in the prior applications.

It is believed that this Information Disclosure Statement is being filed prior to the mailing date of the first Office Action on the merits in the application and pursuant to 37 C.F.R. §1.97(b)(3).

While it is believed that no fee is due in connection with this filing, the Commissioner is hereby authorized to charge any payment of fees or credit any over-payment associated with this application to Deposit Account No. 18-0586.

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10

EXPRESS MAIL Mailing Label Number: <u>EV 482562743 US</u> Date of Deposit: <u>April 4, 2005</u>

I hereby certify that this paper and/or fee is being deposited with the United States Postal Service, "EXPRESS MAIL – POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10, on the date indicated above, and is addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450

(Name of person mailing paper.)

(Signature of person mailing paper.)

Respectfully submitted,

Thomas L MeWilliams Registration No. 44,930

REED SMITH LLP 2500 One Liberty Place 1650 Market Street

Philadelphia, PA 19103-7301

(215) 241-7939

Attorney for Applicants

PORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
(MODIFIED) PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. 04-40081-US

SERIAL NO. 10/782,398

APR 0 4 2005

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Bruce K. Redding JR.

(Use several sheets if necessary)
(USE SEVERAL SHEETS OF THE SEVER

FILING DATE February 18, 2004

APPLICANT

GROUP 3763

EXAMINE	T							U.S. PATENT			T	FILING DATE
R INITIAL	_	T	PATE	NT NI	JMBE	R	 -	DATE	PATENTEE	CLASS	SUBCLASS	IF APPROPRIAT
	4	5	9	2	7	5	3	06/03/1986	Panoz			
	4	6	5	7	5	4	3	04/14/1987	Langer et al.			
	4	7	6	7	4	0	2	08/30/1988	Kost et al.			
	4	7	8	0	2	1	2	10/20/1988	Kost et al.			
	4	7	8	7	8	8	8	11/29/1988	Fox			
	4	8	2	1	7	4	0	04/18/1989	Tachibana et al.			
	4	9	5	3	5	6	5	09/04/1990	Tachibana et al.			
	4	9	7	8	4	8	3	12/18/1990	Redding, Jr.			
	4	9	9	9	8	1	9	03/12/1991	Newnham et al.			
	5	0	0	7	4	3	8	04/16/1991	Tachibana et al.			
	5	0	1	6	6	1	5	05/21/1991	Driller et al.			
	5	1	1	5	8	0	5	05/26/1992	Bommannan et al.			
	5	1	7	1	2	1	5	12/15/1992	Flanagan			
	5	2	0	9	8	7	9	05/11/1993	Redding, Jr.			
1	5	2	3	1	9	7	5	08/03/1993	Bommannan et al.			
	5	2	6	7	9	8	5	12/07/1993	Shimada et al.			
	5	2	7	1	8	8	1	12/21/1993	Redding, Jr.			
	5	2	7	6	6	5	7	01/04/1994	Newnham et al.			
	5	2	8	2	7	8	5	02/01/1994	Shapland et al.			
	5	3	2	3	7	6	9	06/28/1994	Bommannan et al.			
	5	4	0	5	6	1	4	04/11/1995	D'Angelo			
	5	4	2	1	8	1	6	06/06/1995	Lipkovker			_
	5	4	4	5	6	1	1	08/29/1995	Eppstein et al.	:		
	5	4	5	5	3	4	2	10/03/1995	Redding, Jr.			
EXAMINI			12	15	1			10/03/1993	DATE CONSIDERE		I	<u> </u>

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Page	1	of	5	
Iagu		VI.	J	

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (MODIFIED) PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTY. DOCKET NO. 04-40081-US

SERIAL NO. 10/782,398

APPLICANT

Bruce K. Redding JR.

(Use several sheets if necessary)

(37 CFR 1.98(b))

FILING DATE February 18, 2004 GROUP 3763

								U.S. PATENT I	DOCUMENTS			
EXAMINE R INITIAL		l	PATE	NT NU	JMBE	R		ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5	4	5	8	1	4	0	10/17/1995	Eppstein et al.			
	5	4	6	0	7	5	6	10/24/1995	Redding, Jr.			
	5	5	8	2	5	8	6	12/10/1996	Tachibana et al.			
	5	6	3	6	6	3	2	06/10/1997	Bommannan et al.	<u>.</u>		
	5	6	5	8	2	4	7	08/19/1997	Henley			
	5	7	2	9	0	7	7	03/17/1998	Newnham et al.			
	5	8	1	4	5	9	9	09/29/1998	Mitragotri et al.			
	5	9	4	7	9	2	1	09/07/1999	Johnson et al.			
	6	0	0	2	9	6	1	12/14/1999	Mitragotri et al.			
	6	0	1	8	6	7	8	01/25/2000	Mitragotri et al.			
	6	0	2	4	7	1	7	02/15/2000	Ball et al.			
	6	0	3	0	3	7	4	02/29/2000	McDaniel	ļ		
	6	0	4	1	2	5	3	03/21/2000	Kost et al.			
	6	1	9	0	3	1	5	02/20/2001	Kost et al.			
	6	2	3	4	9	9	0	05/22/2001	Rowe et al.			
	6	3	2	2	5	3	2	11/27/2001	D'Sa et al.			
	4	8	7	8	8	9	2	11/07/1989	Sibalis et al.			
	5	1	3	5	4	7	9	08/04/1992	Sibalis et al.			
	5_	3	2	8	4	5	2	07/12/1994	Sibalis et al.			
	6	6	1	4	1	4	3	09/02/2003	Zhang et al.			
	5	7	0_	6	9	5	0	01/13/1998	Houghton et al.			,
	4	7	8	7	8	8	8	11/29/1988	Fox			
	6	1	7	1	2	9	4	01/09/2001	Southam et al.		_	
	5	9	7	8	7	0	1	11/02/1999	Johnson et al.			
	6	5	6	9	0	9	9	05/27/2003	Babaev			
	6	6	6	3	5	5	4	12/16/2003	Babaev			

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Page ____2___ of ____5___

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (MODIFIED) PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTY. DOCKET NO. 04-40081-US	SERIAL NO. 10/782,398	
APPLICANT Bruce K. Redding JR.	<u> </u>	
FILING DATE	GROUP	

3763

(Use several sheets if necessary) (37 CFR 1.98(b))

OTHER DOCUMENTS (Including Author Title Date Relevant Pages Place of Publication)

February 18, 2004

OTHER DOCON	TENTS (Including Author, Title, Date, Nelevant Pages, Place of Publication)
	Amsden, B.G., et al., "Transdermal Delivery of Peptide and Protein Drugs. An Overview", Dept. of Chem. Eng., Queens Unv., Canada, AIChE Journal, vol. 41, No. 8, August 1995, pp. 1972-1997.
	Ben-Jebria, Abdellaziz, et al. "Large Porous Particles for Sustained Proection from Carbachol-Induced Bronchoconstruction in Guinea Pigs", Pharm Research, Plenum Pub. Corp., vol. 16, No. 4, Jan. 1999, pp. 555-561.
	Blankschtein, Daniel, et al., "Transdermal Drug Delivery Using Low-Frequency Sonophoresis", Pharmaceutical Research, Plenum Pub. Corp., vol. 13, No. 3, 1996, pp. 411-421.
	Blankschtein, Daniel, et al., Evaluation of Solute Permeation Through the Stratum Corneum: Lateral Bilayer Diffusion as the Primary Transport Mechanism", J. of Pharm. Sci., vol. 86, No. 10 October 1997, pp. 1162-1172.
	Blankschtein, Daniel, et al., Permeation of Steroids Through Human Skin", J. of Pharm. Sci., vol. 84, No. 9, Sept. 1995 pp. 1144-1146.
	Edward, David A. and Langer, Robert, "A Linear Theory of Transdermal Transport Phenomena", J. of Pharm. Sci vol. 83, No. 9, Sept. 1994, pp. 1315-1334.
	Edwards, David A., et al., "Hydrogels with Enhanced Mass Transfer for Transdermal Drug Delivery", Dept. of Chem Eng., and Dept. of Bioeng. Penn State Univ.
	Edwards, David A., et al., "Recent Advances in Pulmonary Drug Delivery Using Large, Porous, Inhaled Particles", Dept. of Chem. Eng., Penn State Univ., and Dept. of Eng. M.I.T., Amer. Physiological Society, 1998, pp. 379-385.
	Edwards, David A., et al., "Large Porous Particles for Pulmonary Drug Delivery", Sci. Magazine vol. 276, June 20, 1997, pp. 1868-1871.
	Forslind, Bo, Docent, MD, PhD., "Biophysical Studies of Human Skin Barrier and Physiology", EDRG, Med. Biophysics, Dept., Of Med. Biochem. & Biophys. Karolinska Institute, www.mbb.ki.se/forsk/bf.html (9-25-00) pp. 1-2.
	Guy, Richard H., et al., "Transdermal Drug Delivery", http://pharmal.cur-archamps.fr/~guy/lecture.html , pp. 1-29.
	Kost, J., et al., "Transdermal Monitoring of Glucose and Other Analytes Using Ultrasound", Nature Medicine vol. 6, No. 3, March 2000, pp. 347-350.
	Mitragotri, Samir, et al., "Ultrasound-Mediated Transdermal Protein Delivery", Science 269:850-853 (1995).
	Mitragotri, S., et al., "Non-Invasive Drug Delivery and Diagnostics Using Low-Frequency Sonophoresis", Encl. of Pharm. Tech, Swarbrick and Bovian, Editors, vol. 14, Marcel Dekker, Inc., (1995).
EXAMINER	DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Page	3	of	5	

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE (MODIFIED)

(37 CFR 1.98(b))

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY.	DOCKET	NO
04-4008	1-US	

SERIAL NO. 10/782,398

APPLICANT

Bruce K. Redding JR.

FILING DATE February 18, 2004

GROUP 3763

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	Mitragotri, S., et al., "A Mechanistic Study of Ultrasonically-Enhanced Transdermal Drug Delivery", (1995) Journal of Pharm. Sci. vol. 84, No. 6, pp. 697-706.
	Osborne, David W. and Henke, Jill J., "Skin Penetration Enhancements Cited in the Technical Literature", (9-25-00) R&D, Vivotex Corp., www.pharmtech.com/technical/osborne/osborne.html , pp. 1-26.
	Ristic, Cedomila, "Modeling of Ultrasonic Convection Dispension Mass Transfer Enhancement in Porous Membranes"
	Ritter, Timothy, et al., "High Frequency Transducer Arrays for Medical Imaging", Medical Imaging 2000, SPIE vol. 3982, pp. 208-216.
	Saunders, James, et al., "A Novel Skin Penetration Enhancer: Evaluation by Membrane Diffusion and Confocal Microscopy", J. Pharm. Sci, (www.ualberta.ca/~csps), 2(3):99-107 1999.
	Wang, Haifeng, et al., "High Frequency Properties of Passive Materials for Ultrasonic Transducers", IEEE Transactions on Ultrasonics, Ferroelectrics, and Freq. Control vol. 48, No. 1, Jan. 2001, pp 78-83.
	Wang, Heifeng, et al., "Passive Materials for High Frequency Ultrasound Transducers", SPIE Conference on Ultrasonic Trans. Eng., SPIE vol. 3664, Feb. 1999, pp. 35-42.
	Wang, Jue, et al., "Inhalation of Estradiol for Sustained Systemic Delivery", J. of Aerosol Medicine vol, 12, No. 1, 1999, pp. 27-36.
	Roberts, Dottie, "Transdermal Drug Delivery Using Iontophoresis and Phonophoresis", Orthopaedic Nursing, May 1999, vol. 18, i3, pp 50, (http://web4.infotrac.galegroup.com), pp 1-8.
	Byl, Nancy N., "The Use of Ultrasound as an Enhancer for Transcutaneous Drug Delivery" Phonophoresis, Physical Therapy, June 1995, vol. 75 No. 6, pp. 89(15), (http://web4.infotrac.gale rgoup.com), pp. 8-28.
	Cameron, Michelle H., et al., "Relative Transmission of Ultrasound by Media Customarily Used for Phonophoresis", Physical Therapy, Feb. 1992, vol. 72, No. 2, pp. 142(7), (http://web4.infotrac.galegroup.com), pp. 28-35.
	Ciccone, Charles D., et al., "Effects of Ultrasound and Trolamine Salicylate Phonophoresis on Delayed- Onset Muscle Soreness", Physical Therapy, Sept. 1991, vol. 71, No. 9, pp. 666(13), (http://web4.infotrac.galegroup.com), pp. 35-48.
	Newman, Laura, Contributing Editor, "Iontophoresis Delivers Painless, Noninvasive Anesthesia", Dermatology Times, Apr. 1995 vol. 16, Issue 4, p. 34.
	Love, APRN, MSN, Georgette, "Electrifying News About Iontophoresis", Nursing200 0, vol. 30 No. 1, (2000), pp. 48-49.
EXAMINER	DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Page	4	of	5	
raue	•	()	23	

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE (MODIFIED)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTY. DOCKET NO.	SERIAL NO.
04-40081-US	10/782,398
APPLICANT	
Bruce K. Redding JR.	
C	
EN INC DATE	CROUP

(Use several sheets if necessary)

3763 (37 CFR 1.98(b)) February 18, 2004 OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication) Griffin, James E. Ph.D., "Physiological Effects of Ultrasonic Energy as it is Used Clinically", J. of the Amer. Phys. Ther. Assoc., vol. 46, No. 1, Jan. 1966, pp. 18-26. Girish, Rao, et al., "A noninvasive Approach for Glucose Monitoring", Plenum Publishing Corporation, 1993, pp. 1751-1755. Griffin, James E., Ph.D., et al., "Patients Treated with Ultrasonic Driven Hydrocortisone and with Ultrasound Alone", Physical Therapy, vol. 47, No. 7, pp. 594 -601. McElnay, James C., et al., "Phonophoresis of Methyl Ncotinate: A Preliminary Study to Elucidate the Mechanism of Action", Pharm. Research, vol. 10, No. 12, 1993, pp. 1726 -1731. French, Edward J, et al., "Mechanisms and Prediction of Nonionic Surfactant Effects on Skin Permeability", Pharm. Skin Penetration Enhancement, vol. 59, 1993, Marcel Dekker, Inc., pp. 113 -143. McElnay, James C., et al., "The Use of Ultrasound in Skin Penetration Enhancement", Drugs and The Pharmaceutical Sciences, Pharmaceutical Skin Penetration Enhancement, vol. 59, 1993, Marcel Dekker, Inc., pp. 293-309. Turner, Norris G., et al., "Visualization of Stratum Comeum and Transdermal Permeation Pathways", Drugs and The Pharmaceutical Sciences, Mechanisms of Transdermal Drug Delivery, vol. 83, 1997, Marcel Dekker, Inc., pp. 1-40. Sun, Ying, "Skin Absorption Enhancement by Physical Means: Heat, Ultrasound, and Electricity", Transdermal and Topical Drug Delivery Systems, 1997, Interpharm Press, Inc., pp. 327 -355. EXAMINER **DATE CONSIDERED**

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

_	_	_	_	
Page	5	of	5	